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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,923	12/30/1999	ADNAN SHENNIB	ISM/012	7053

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/475,923	Applicant(s) SHENNIB ET AL.	
	Examiner Phylesha L Dabney	Art Unit 2643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This action is in response to the amendment filed on 28 February 2002 in which claims 1-94 are pending. Applicant's arguments have been fully considered but they are not persuasive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 3, 9, 13, 20-22, 24-25, 30, 34-36, 41-83, 85, 87-89 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 13-17, 23, 28, 38-41, 44, 46, 47, 68, and 77 of U.S. Patent No. 6,137,889. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the claims in the present application are covered by the scope of the claims in the patent with obvious wording variations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1, 3-9, 13-16, 19-30, 32-37, 39-53, 55-74, 77, 79, and 81-94 are rejected under 35 U.S.C. 102(e) as being anticipated by Shennib et al (U.S. Patent No. 6,137,889).

Regarding claim 1, Shennib discloses a statically floating filament assembly (38) constructed and adapted to fit within the ear canal of an individual for contacting the tympanic membrane directly and imparting audible vibrations thereto, the filament assembly (38) being dynamically coupled to a stationary vibration force element (40) positioned in the ear canal at a distance from the tympanic membrane, the filament assembly comprising:

(a) a vibratory element (31) adapted to be laterally positioned when the filament assembly is fitted within the ear canal, and arranged to respond to dynamic forces imparted by the vibrational force element, and

(b) a vibrational shaft element (30) extending medially for transferring audible vibrations from the vibratory element (31) to the tympanic membrane when the filament assembly is fitted within the ear canal,

the filament assembly (38) being freely movable within an operable range with respect to the vibration force element, thereby allowing individual adjustment and positioning of the

filament assembly for contacting the tympanic membrane and imparting audible vibrations without exerting static forces thereto (see figures 5-11).

Regarding claim 3, Shennib discloses the vibrational shaft is radially flexible (col. 10 lines 30-43; col. 11 lines 3-7; col. 17 lines 4-11).

Regarding claim 4, Shennib discloses the length of the filament assembly is at least 6 mm (col. 10 lines 55-57 and col. 16 lines 57-62).

Regarding claim 5, Shennib discloses the diameter of the vibrational shaft element and the vibratory element (31) is less than 0.4mm (col. 16 line 57 thru col. 17 line 53).

Regarding claim 6, Shennib discloses the ratio of length of the filament assembly to diameter of the vibrational shaft element (col. 10 lines 55-57 and col. 16 line 57 thru col. 17 line 30).

Regarding claims 7 and 43, Shennib discloses the filament assembly (38) is separable from the vibrational force element (40) for placement and replacement therein (col. 9 line 53 thru col. 10 line 13).

Regarding claim 8, Shennib discloses the filament assembly weights less than 20 mg (col. 10 lines 63-65).

Regarding claims 9, 44, and 45, Shennib discloses the vibratory element (31) comprises a magnetic material (36, col. 9 lines 31-45) which vibrates in response to a magnetic field produced from the vibration force element (40).

Regarding claims 13 and 47, Shennib discloses a tympanic coupling element (31) adapted to contact the tympanic membrane for transferring the audible vibrations thereto.

Regarding claim 14, Shennib discloses the tympanic coupling element (31) is articulated with respect to the vibrational shaft element (30) via an articulation joint (col. 9 lines 31-45).

Regarding claims 15-16, Shennib discloses the articulation joint (col. 9 lines 31-45) comprises a rounded edge (37, ball) and a recess (36, socket) with magnetic attraction therebetween.

Regarding claim 19, Shennib discloses the vibrational shaft element comprises a rigid material selected form a group comprising metal and plastics (col. 17 lines 4-11).

Regarding claims 20 and 49, Shennib discloses the tympanic coupling element is removably attachable to the tympanic membrane by means providing a relatively weak adhesion force (col. 8 lines 48-65).

Regarding claims 21 and 50, Shennib discloses the relatively weak adhesion force means includes a layer of biocompatible agent between the tympanic coupling element and the tympanic membrane for providing adhesion therebetween (col. 8 lines 48-65).

Regarding claims 22 and 51, Shennib discloses the biocompatible agent is selected from a group comprising gel and oil(col. 8 lines 59-62).

Regarding claim 23, Shennib discloses the biocompatible agent is non-drying for providing long term adhesion between the tympanic coupling element (31) and the tympanic membrane (col. 8 lines 54-59).

Regarding claims 24 and 52, Shennib discloses the tympanic coupling element (31) is self-centering with respect to the umbo area of the tympanic membrane during attachment thereto (col. 10 lines 44-52).

Regarding claim 25, Shennib discloses the tympanic coupling element (31) is arranged and adapted for surgical attachment to one of either the tympanic membrane or malleus (col. 9 lines 7-17).

Regarding claims 26-27 and 53, Shennib discloses the tympanic coupling element (31) is umbrella shaped (col. 10 lines 44-53).

Regarding claims 28-29, Shennib discloses the tympanic coupling element (31) comprises a conforming surface selected from a group comprising silicone, rubber, and gel (col. 9 lines 1-6).

Regarding claim 30, Shennib discloses the tympanic coupling element is composed of oxygen permeable material (col. 9 lines 46-52).

Regarding claims 32 and 69, Shennib discloses the vibrational force element (40) comprises an electromagnetic coil (col. 11 line 57 thru col. 12 line 23).

Regarding claims 33 and 70, Shennib discloses the electromagnet coil (col. 11 line 57 thru col. 12 line 23) comprises an air-core (col. 18 lines 23-56) for accepting the filament assembly.

Regarding claims 34 and 71, Shennib discloses the vibration force element (40) comprises a vibrating element (41, 81) for directly vibrating the vibratory element (31) of the filament assembly.

Regarding claims 35-36 and 55-56, Shennib discloses the filament assembly conducts audible vibrations at least partially by means of axial and rocking motion (col. 11 lines 35-40).

Regarding claim 37, Shennib discloses the filament assembly comprises an elongated thin strip selected from a group comprising piezoelectric, piezomagnetic or magnetostrictive elements (col. 12 lines 29-33).

Regarding claims 39 and 79, Shennib discloses the filament assembly comprising lubricous means for minimizing contact friction of the filament assembly with the vibration force element (col. 8 line 53 col. 9 line 17).

Regarding claims 40 and 81, Shennib discloses the filament assembly comprising medication material selected form a group including anti-bacterial, anti-fungal, and anti-microbial agents (col. 8 line 53 thru col. 9 line 17).

Regarding 41, Shennib discloses a canal hearing device (50, 70) adapted for directly contacting the tympanic membrane and imparting audible vibrations thereto, comprising:

a floating filament assembly (38); a stationary vibration force element (40) positioned in the ear canal at a distance from the tympanic membrane, the filament assembly (38) being responsive to dynamic forces imparted thereon by the vibration force element for movement freely within an operable range in at least one degree of freedom with respect to the vibration force element, thereby allowing individual adjustment and positioning of the filament assembly for contacting the tympanic membrane and imparting audible vibrations without exerting static forces thereto (see figures 5-11).

Regarding claim 42, see rejection of claims 5 and 6.

Regarding claim 46, see rejection of claim 34.

Regarding claim 48, see rejection of claims 14 and 15.

Regarding claim 57, Shennib discloses the hearing device including a retainer means (56).

Regarding claim 58, Shennib discloses the retainer means comprises one or more pairs of foldable wings (figures 13 and 14).

Regarding claim 59, Shennib discloses the retainer means (56) comprises a biocompatible adhesive (col. 12 lines 66-67).

Regarding claim 60, as shown in the figures, Shennib discloses a hearing aid constructed and adapted to be worn completely within the ear canal.

Regarding claim 61, as shown in the figures, Shennib disclose the hearing device (50) is constructed and adapted to be positioned substantially within the bony portion (13) of the ear canal.

Regarding claim 62, Shennib disclose the hearing device provides a highly energy efficient system to enable the hearing device to be operational in the ear canal of the wearer for a period exceeding two months (col. 14 lines 30-33 and also claim 47 of 6,137,889).

Regarding claim 63, Shennib discloses the hearing device including remote control means (col. 13 line 61 thru col. 14 line 12, and col. 15 lines 2-53).

Regarding claim 64, Shennib discloses the hearing device including a magnetically activated switch (91, 145), and wherein the remote control means (95, 140) comprises an external magnetic device (96, 98, 141-142).

Regarding claim 65, Shennib discloses the hearing device including a debris guard (57) for protecting the microphone (51).

Regarding claim 66, Shennib discloses the hearing device having a plurality of removable disposable elements including the filament assembly (38), a battery (54), an acoustically transparent guard (57), an acoustic screen (59), and a retainer (56).

Regarding claim 67, Shennib discloses the hearing device having an external fitting system connectable to the canal hearing device for conducting audiometric evaluation, device programming and fitting prescription for subject wearing the hearing device (col. 14 lines 44-67).

Regarding claim 68, Shennib discloses the hearing device comprising a wireless receiver (71) for receiving wireless signals (97) representative of audio signals from an external audio transmitter, the hearing device being responsive to received wireless signals.

Regarding claim 72, Shennib discloses the vibrational force element comprises a shield (43, 56, 57, 69) for minimizing at least one electrical noise signal or magnetic noise signal.

Regarding claims 73 and 74, Shennib discloses the hearing device (50, 70) comprising means (43, 56, 57, 69) for rendering the hearing device substantially non-occlusive within the ear canal.

Regarding claim 77, Shennib discloses a means of manipulating the vibrational filament assembly for attachment to the tympanic membrane in corporation with probe tube and corresponding acoustic probe tube measurements (110).

Regarding claim 82, see rejection of claims 1 and 14-16, 41, or claims 41 and 48.

Regarding claim 83, Shennib discloses a hearing device constructed and adapted to fit and be worn within the ear canal of a human subject for imparting audible vibrations to the tympanic membrane of the subject, comprising: a microphone (51); an amplifier (53); a vibration

force element (40); and a vibrational filament assembly (30, 31), the vibrational filament assembly being essentially free floating within an operable range in at least one degree of freedom with respect to the vibration force element, thereby allowing individual adjustment and positioning of the vibrational filament assembly for contacting the tympanic membrane and imparting audible vibrations without exerting essentially any static forces thereto.

Regarding claim 84, Shennib discloses the vibrational filament assembly (30, 31) comprising: an umbrella-shaped tympanic coupling element (31) for contacting and adhering to the tympanic membrane and conducting vibrations thereto; and a vibrational conductive shaft (30) articulated with the tympanic coupling element.

Regarding claim 85, see rejection of claim 41.

Regarding claim 86, see rejection of claim 47.

Regarding claim 87, see rejection of claim 49.

Regarding claim 88, see rejection of claim 50.

Regarding claim 89, Shennib discloses pre-coating the tympanic membrane with a liquid agent for adhering the tympanic coupling element (31) to the tympanic membrane (col. 8 lines 54-62).

Regarding claims 90 and 91, see rejection of claim 48.

Regarding claim 92, see rejection of claim 52.

Regarding claims 93 and 94, Shennib discloses a method of manipulating and attaching a floating vibrational filament assembly to the tympanic membrane, including dynamically coupling the floating vibrational filament assembly (30, 31) to a vibration force element (40), and performing the manipulating and attaching of the floating vibrational filament assembly to

the tympanic membrane by means incorporating any direct visualization, optical fiber visualization and acoustic probe tube measurements (110).

Response to Arguments

3. With respect to the applicant's arguments pertaining to the Double Patenting rejection, the Applicant states that the prior art (Shennib '889) seeks to minimize static pressure on the tympanic membrane, where as the present invention eliminates static pressure. In response to applicant's argument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). First, as shown in fig. 8, Shennib ('889) teaches an example of a vibratory element dynamically coupled to a filament assembly. This clearly shows the patent satisfies the requirement that the two structural elements must be dynamically coupled. In addition, as shown in fig. 11, Shennib ('688) teaches the filament assembly undergoing a rocking motion which satisfies the requirement that the filament assembly must freely move, in at least a one degree of freedom, within a operable range relative to the vibration force element.

4. Due to the applicant's statements on page 13 lines 6-7, claims 41-81 have been included in the Double Patenting rejection above.

5. With respect to the arguments related to the International Preliminary Examination Report presented on page 15, the patent date of the Shennib ('889) was disqualified from be used in the rejection of PCT/US00/34265.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phylesha L Dabney whose telephone number is 703-306-5415. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, Fridays 8:30-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Kuntz can be reached on 703-305-4708. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9314 for regular communications and 703-872-9314 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-4700.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 872-9314, for formal communications intended for entry and for informal or draft communications, please label "Proposed" or "Draft" when submitting an informal amendment.

(703) 306-0377, for customer service questions.

Hand-delivered responses should be brought to Crystal Park II, 2121 Crystal Drive, Arlington, VA., Sixth Floor (Receptionist).

PLD
May 17, 2002

CURTIS KUNTZ
SUPERVISORY PATENT EXAMINER
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